



PTO/SB-08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

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|------------------------|-----------------------|
| Application Number | 10/378,956 Pkt 0, 702 |
| Filing Date | September 11, 2003 |
| First Named Inventor | Örn Almarsson |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | TPI-350C1 |

Sheet 1 of 2

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number Number - Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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| | U2 | US- | | | |
| | U3 | US- | | | |
| | U4 | US- | | | |
| | U5 | US- | | | |
| | U6 | US- | | | |
| | U7 | US- | | | |
| | U8 | US- | | | |
| | U9 | US- | | | |

FOREIGN PATENT DOCUMENTS

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|--------------------|-----------------------|--|--------------------------------|--|---|----------------|
| 1ACI | F1 | GB 1 297 261 A | 11-22-1972 (22 Nov 1972) | E.R. Squibb & Sons, Inc. | whole document | |
| | F2 | | | | | |
| | F3 | | | | | |
| | F4 | | | | | |
| | F5 | | | | | |
| | F6 | | | | | |
| | F7 | | | | | |

Examiner
Signature

/Abigail Cotton/ (03/20/2007)

Date
Considered

03/20/2007

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| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/378,956-1/160,222 |
| | | | | Filing Date | September 11, 2003 |
| | | | | First Named Inventor | Örn Almarsson |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 2 | of | 2 | Attorney Docket Number | TPI-350C1 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| /AC/ | R1 | BRADER, M.L. <i>et al. Nature Biotechnol.</i> , 2002, 20 :800-804. | |
| /AC/ | R2 | EL-NAHHAS, S.A. <i>Pharmazie</i> , 1996, 51(12):960-963. | |
| /AC/ | R3 | FLEISCHMAN, S.G. <i>et al. Crystal Growth & Design.</i> , 2003, 3(6): 909-919. | |
| /AC/ | R4 | OSWALD, I.D.H. <i>et al. Acta Cryst.</i> , 2002, B58:1057-1066. | |
| /AC/ | R5 | REYNOLDS, J.E.F. (ed). Martindale, The Extra Pharmacopoeia, 1993, The Pharmaceutical Press, London, England, 13 th Edition, pp. 1431 (e.g., Acetaminophen, Aspirin, and Caffeine Tablets), 1465 (e.g., Aspirin plus C), 1521 (Cofafen Continus), 1610 (Gaboril Complex). | |
| /AC/ | R6 | WALSH, R.D. Bailey <i>et al. Chem. Commun.</i> , 2003, 2003:186-187. | |
| | R7 | | |
| | R8 | | |
| | R9 | | |
| | R10 | | |
| | R11 | | |
| | R12 | | |
| | R13 | | |

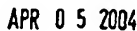
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| Examiner Signature | /Abigail Cotton/ (03/20/2007) | Date Considered | 03/20/2007 |
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| Application Number | 10/660,202 |
| Filing Date | September 11, 2003 |
| First Named Inventor | Orn Almarsson |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | TPI-350C1 |

U. S. PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ² |
| | | Country Code ³ Number ⁴ Kind Code ⁶ (if known) | | | | |
| IAC/ | 1 | WO 03/074474 A2 | 09-12-2003 | Zaworotko et al | Pls review all | |
| IAC/ | 2 | WO 03/033462 A2 | 04-24-2003 | Matzger et al. | Pls review all | |
| IAC/ | 3 | WO 01/51919 A2 | 07-19-2001 | Levinson et al. | Pls review all | |
| IAC/ | 4 | WO 01/42222 A1 | 06-14-2001 | Ferro et al. | Pls review all | |
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Application Number 10/660,202

Filing Date September 11, 2003

First Named Inventor Orn Almarsson

Art Unit

Examiner Name

Attorney Docket Number TPI-350C1

Sheet

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of

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NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-----------------------|--------------------------|---|-------------------------------------|
| /ACI/ | 5 | WEISSBUCH, I. et al., "Understanding and Control of Nucleation, Growth, Habit, Dissolution and Structure...", Acta Cryst. (1995), pp. 115-148, vol. B51 | <input checked="" type="checkbox"/> |
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Examiner
Signature

/Abigail Cotton/ (03/20/2007)

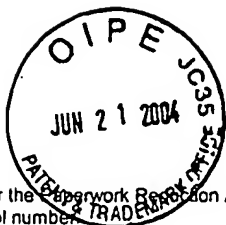
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| | U7 | US- | | | |
| | U8 | US- | | | |
| | U9 | US- | | | |

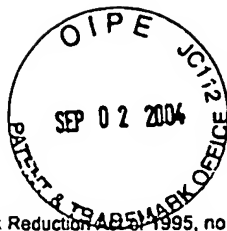
| FOREIGN PATENT DOCUMENTS | | | | | | |
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| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁴ |
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| IAC/ | F1 | WO 02/056878 A2 | 07-25-2002 | Pharmacia Corp. | All | — |
| IAC/ | F2 | WO 01/41536 A2 | 06-14-2001 | Pharmacia Corp. | All | — |
| IAC/ | F3 | EP 1167355 A1 | 01-02-2002 | Fako Ilacari A.S. | All | — |
| | F4 | | | | | |
| | F5 | | | | | |
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| | | | | Application Number | 10/606,202 |
| | | | | Filing Date | September 11, 2003 |
| | | | | First Named Inventor | Orn Almarsson |
| | | | | Art Unit | 1653 |
| | | | | Examiner Name | |
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| | | Country Code ³ | Number ⁴ - Kind Code ⁵ (if known) | | | |
| IAC | F1 | | WO 01/42221 A1 | 06-14-2001 | Pharmacia Corp. | All |
| | F2 | | | | | |
| | F3 | | | | | |
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| | F6 | | | | | |
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| | | | First Named Inventor | Örn Almarsson | |
| | | | Art Unit | 1617 | |
| | | | Examiner Name | Leonard Williams | |
| Sheet | 1 | of | 36 | Attorney Docket Number | TPI-350C1 |

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| | U2 | US-4,198,507 | 04-15-1980 | Barry, <i>et al.</i> | All |
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| ✓ | U19 | US-2004/0019211 | 01-29-2004 | Remenar, <i>et al.</i> | All |
| | U20 | US-2004/0106052 | 06-03-2004 | Molaire | All |

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| | | | Application Number | 10/660,202 | |
| | | | Filing Date | September 11, 2003 | |
| | | | First Named Inventor | Örn Almarsson | |
| | | | Art Unit | 1617 | |
| | | | Examiner Name | Leonard Williams | |
| Sheet | 2 | of | 36 | Attorney Docket Number | TPI-350C1 |

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| Examiner Signature | /Abigail Cotton/ (03/20/2007) | Date Considered | 03/20/2007 |
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| | | | Application Number | 10/660,202 | |
| | | | Filing Date | September 11, 2003 | |
| | | | First Named Inventor | Örn Almarsson | |
| | | | Art Unit | 1617 | |
| | | | Examiner Name | Leonard Williams | |
| Sheet | 3 | of | 36 | Attorney Docket Number | TPI-350C1 |

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| Examiner Signature | /Abigail Cotton/ (03/20/2007) | Date Considered | 03/20/2007 |
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| | | | Application Number | 10/660,202 | |
| | | | Filing Date | September 11, 2003 | |
| | | | First Named Inventor | Örn Almarsson | |
| | | | Art Unit | 1617 | |
| | | | Examiner Name | Leonard Williams | |
| Sheet | 4 | of | 36 | Attorney Docket Number | TPI-350C1 |

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| Examiner Signature | /Abigail Cotton/ (03/20/2007) | Date Considered | 03/20/2007 |
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| | | | First Named Inventor | Örn Almarsson | |
| | | | Art Unit | 1617 | |
| | | | Examiner Name | Leonard Williams | |
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| Examiner Signature | /Abigail Cotton/ (03/20/2007) | Date Considered | 03/20/2007 |
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| Sheet | 6 | of | 36 | Attorney Docket Number | TPI-350C1 |

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|-----------------------|-------------------------------|--------------------|------------|
| Examiner Signature | /Abigail Cotton/ (03/20/2007) | Date Considered | 03/20/2007 |
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| | | | | Application Number | 10/660,202 | |
| | | | | Filing Date | September 11, 2003 | |
| | | | | First Named Inventor | Örn Almarsson | |
| | | | | Group Art Unit | 1617 | |
| | | | | Examiner Name | Leonard Williams | |
| Attorney Docket Number | TPI-350C1 | | | | | |
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| | F33 | WO | 03 033462 A2 | 04-23-2003 | Regents of Univ. Mich. | All |
| | F34 | WO | 01 51919 A2 | 07-19-2001 | Transform Pharm. Inc. | All |
| | F35 | WO | 01 42222 A1 | 06-14-2001 | Pharmacia Corp. | All |
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| | F38 | WO | 01/41760 A3 | 06-14-2001 | Pharmacia Corporation | All |
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| V | F41 | WO | 02/00627 A1 | 01/03/2002 | Fako Ilaciari A.S. | All |
| | F42 | IN | 182620 | 12-24-1994 | Bajaj et al. | All |

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| | | | First Named Inventor | Örn Almarsson | |
| | | | Group Art Unit | 1617 | |
| | | | Examiner Name | Leonard Williams | |
| Sheet | 8 | of | 36 | Attorney Docket Number | TPI-350C1 |

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| | R10 | JACKISCH, M. <i>et al.</i> "Structures of three related biphenyl compounds: 4,4'-biphenyldiol, 3,3',5,5'-tetra- <i>tert</i> -butyl-4,4'-biphenyldiol, and 3,3',5,5'-tetra- <i>tert</i> -butyl-1,1'-bicyclohexa-2,5-dienylidene-4,4'-dione" <i>Acta Cryst.</i> , 1990, pp. 919-922, Vol. C46. | |
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| /ACI/ | R16 | LYNCH, D. <i>et al.</i> "Molecular cocrystals of carboxylic acids. XV. Preparation and characterization of heterocyclic base adducts with a series of carboxylic acids, and the crystal structures of the adducts of 2-aminopyrimidine with 2,6-dihydroxybenzoic acid, 4-aminobenzoic acid, phenoxyacetic acid, (2,4-dichlorophenoxy) acetic acid, (3,4-dichlorophenoxy)- acetic acid and salicylic acid, and 2-aminopyridine with 2,6-dihydroxybenzoic acid" <i>Aust. J. Chem.</i> , 1994, pp. 1097-1115, Vol. 47. | | |
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| IAC/ | R25 | NAKANISHI, I. <i>et al.</i> "X-ray structural studies on two forms of β -cyclodextrin barbitol complexes" <i>Journal of Inclusion Phenomena</i> , 1984, pp. 689-699, Vol. 2. | | |
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| | | | First Named Inventor | Örn Almarsson | |
| | | | Group Art Unit | 1617 | |
| | | | Examiner Name | Leonard Williams | |
| Sheet | 13 | of | 36 | Attorney Docket Number | TPI-350C1 |

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| | | | | Group Art Unit | 1617 |
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| | | | First Named Inventor | Örn Almarsson | |
| | | | Group Art Unit | 1617 | |
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| | | | Examiner Name | Leonard Williams | |
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| First Named Inventor | Orn Almarsson |
| Art Unit | 1653 |
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| | U3 | US- | | | |
| | U4 | US- | | | |
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